REMARKS/ARGUMENTS

Claims 1-17 are active. Claims 2, 7, 10, 11 and 13 have been cancelled. No other amendments have been made. The Applicants appreciate the withdrawal of the rejections under 35 U.S.C. 112. A Declaration is submitted herewith in further support of the Applicant's response to the remaining obviousness and double patenting rejections.

Rejection—35 U.S.C. §103

Claims 1-17 were rejected under 35 U.S.C. §103(a) as obvious in view of the combination of Leusch (WO 00/56276) and De Sadeleer (US 5,973,212). This rejection cannot be sustained because prior art, even in combination does not suggest a toothpaste with the specific water and erythritol content selected according to Equation 1.

Leusch, the primary reference, was relied upon for teaching the following elements (see p. 4 of the OA):

· oral care compositions, including toothpastes (p. 2, line 3) containing non-cariogenic carbohydrates (p. 2, last three lines-p. 3, line 2), including erythritol (p. 3, line 12).

· compositions containing non-cariogenic carbohydrates, such as erythritol, in an amount ranging from 1 to 65 wt.% (p. 3, line 1).

· exemplifying a composition containing 10% erythritol, xanthan gum, carboxymethylcellulose and 23.56% water (Example IV, p. 19).

· adding "coolants" at page 10, lines 5-8.

While Leusch teaches some of the elements of the invention, such as a toothpaste, it provided no suggestion to make a toothpaste according to claim 1.

Leusch provided no motivation for selecting erythritol instead of some other non-cariogenic carbohydrate and provided no motivation for including it in a toothpaste in an amount of 30-60 wt.% and at the ratio to water as defined by Equation 1.

Leusch taught away from a toothpaste composition where the non-cariogenic carbohydrate is present in an amount that would not dissolve since an objective of Leusch was "treating or preventing the formation of caries" by facilitating the absorption of a non-cariogenic carbohydrates into plaque. This objective is described on page 2, *Brief Summary of the Invention*, which indicates "said polyol is used in a level sufficient to promote greater uptake of said non-cariogenic carbohydrate by plaque". Thus, one would have never been motivated by Leusch to use a concentration of erythritol that was so high that it did not dissolve.

Example IV on page 19 of Leusch, mentioned in the rejection, falls outside of the invention since it describes a composition that contains ***only 10 wt.% erythritol***, well below the amount of erythritol required by claim 1-- 30 wt% minimum. Thus, this Example is not pertinent to the present invention. Moreover, the amount of erythritol (10%) and water (23.56%) in this exemplified composition falls outside of Equation 1 since (23.56% x 0.3) + 25% = 32.07% is significantly greater than 10%.

Leusch, page 10, 2nd full paragraph, does not disclose erythritol as a coolant, but names various classes of menthol-like coolants. Page 10, line 7 of Leusch specifies that the coolant should be "present. . .at a level from about 0.001% to about 10%". Leusch does not describe erythritol as a coolant and even if it did, Leusch teaches away from including it in an amount of more than about 10%. There is not suggestion in Leusch to incorporate erythritol in an amount of 30-60 wt.% as a coolant.

De Sadeleer, col. 2, lines 17-19, was relied upon for teaching erythritol having an average particle size of 200μm or less because Leusch did not disclose this element, see the bottom of p. 4 of the OA. At the bottom of col. 1, De Sadeleer also says that when "dissolved in an aqueous liquid erythritol is known to have a cooling effect". However, while De Sadeleer does teach a particle size range of 10 to 250 microns, it does not suggest including

erythritol particles in a toothpaste composition in an amount ranging form 30-60 wt.% or selecting a ratio of erythritol to water content according to Equation 1. Thus, like Leusch, De Sadeleer does not suggest the content limitations or content ratios required by the present claims. Neither Leusch nor De Sadeleer suggests or provided a reasonable expectation of success for the functional properties attained by the invention and thus no *prima facie* case has been established.

In addition to the lack of any suggestion in the two prior art references for a toothpaste composition formulated according the Equation 1, no *prima facie* case has been established because Leusch and DeSadeleer do not provide a reasonable expectation of success for the superior properties such a toothpaste. Neither Leusch nor De Sadeleer discloses or suggests a toothpaste containing water and the sugar alcohol erythritol in the proportions and ratio required by claim 1. In addition to content limitations of 30-60 wt.% erythritol and 15-30 wt.% water, Equation (1) in claim 1 requires that the amount of water x 0.3 + 25 be less than or equal to the amount of erythritol. This ratio limitation assures that the erythritol in the toothpaste cannot be totally dissolved in the water making up the toothpaste. The undissolved erythritol in the claimed toothpaste provides a cooling sensation since erythritol has a negative heat of solution. The prior art did not recognize the benefit of compounding a toothpaste that contained undissolved erythritol, nor the benefits of careful selection of water and erythritol content to provide superior storage stability and shape retention to a toothpaste in addition to the superior cooling sensation provided by the undissolved erythritol. These superior properties are shown in the table below which is reproduced from the Declaration accompanying this response. The Comparative Examples in this table show the detrimental effects of varying erythritol and water content outside of the ranges or ratios required by claim 1.

	Invention				Comparatives									
	Ex. B	Ex. C	Ex. E	Ex. F	Comp. Ex.5	Comp. Ex.6	Comp. Ex.7	Comp. Ex.8	Comp. Ex.9	Comp. Ex.10	Comp. Ex.11	Comp. Ex.12	Comp. Ex. S	Ref.
Erythritol	60	30	35	60	65	60	30	24	30	35	59.5	64.5	0	0
Water	15	15	30	30	15	10	10	15	30	35	35	30	30	20
Glycerin	0	0	0	0	0	0	0	0	0	0	0	0	0	40
Sorbitol	19.5	49.5	29.5	4.5	14.5	24.5	54.5	55.5	34.5	24.5	0	0	64.5	21.75
Na-Carboxymethyl-cellulose	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	0
Xanthan gum	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.5
Na-Saccharin	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Na-lauryl sulfate	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.5
Abrasive silica	0	0	0	0	0	0	0	0	0	0	0	0	0	10
PEG	2	2	2	2	2	2	2	2	2	2	2	2	2	5
Flavor	1	1	1	1	1	1	1	1	1	1	1	1	1	1.2
Erythritol + sorbitol + water	94.5	94.5	94.5	94.5	94.5	94.5	94.5	94.5	94.5	94.5	94.5	94.5	94.5	41.75
Total amount	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Meets Equation 1? (wt% of water) x $0.3 + 25 \leq$ (wt% of erythritol)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	No	-
Cooling sensation	A	A	B	A	A	A	A	C	C	C	A	A	A	C
Storage stability	B	B	A	B	C	C	C	B	A	A	B	C	C	-
Shape retention-feeling upon use	Good	Good	Very good	Good	Hard	Hard	Good	Good	Good	Good	Bad	Good	Bad	-

As evident from the experimental data above, when the cooling effect, stability and shape retention properties of toothpaste compositions containing identical amounts of sugar alcohol (*i.e.*, erythritol, sorbitol or both) and water but different amounts or ratios of erythritol and water were compared, superior cooling effect, stability and shape retention were attained when the amounts and ratios of erythritol and water according to the invention were selected. There is no suggestion or expectation of obtaining these functionally superior properties in Leusch or De Sadeleer. Accordingly, this rejection cannot be sustained since the prior art did not suggest nor provide a reasonable expectation of success for the invention.

Response to Examiner's Arguments

On page 8, in the paragraph starting on line 4, the Examiner disagrees that Leusch requires that all the erythritol be dissolved and that the amounts of erythritol disclosed by Leusch "encompass and overlap with the amounts recited in the instant claims". The Examiner regards Leusch as generically describing a genus of compositions containing from 1 to 65% erythritol that may also contain water (although as pointed out above, Example VI in Leusch does not correspond to the invention because it contains insufficient erythritol).

On page 9, the Examiner indicates that "one would be motivated to manipulate the erythritol depending on the desired properties. However, as held in *In re Antonie*, 195 USPQ 6, 8-9 (CCPA 1977), there must be evidence in the record that the prior art recognized that particular parameter affected the result. There is no evidence of record here that establishes that erythritol and water content, and the ratio of water to erythritol were known to be results-effective variables.

On page 9, lines 5-6, the Examiner attempts to shift the burden of proof to the Applicant to show the criticality of the amount of erythritol. However, as discussed above, since no *prima facie* case has been established, the burden remains on the Office. Nevertheless, the Applicants have provided herewith controlled comparisons of toothpaste

compositions containing amounts and ratios of erythritol according to the invention as well as comparative examples falling outside the scope of the invention. These data show the superior functional properties attained by making the selections required by claim 1.

On page 9, starting at line 7, the Examiner objected to the previously-submitted experimental data because it was not properly controlled. That objection cannot apply to the data in the attached Declaration in which the sugar alcohol and water content of all the Examples and Comparative Examples was kept constant and only the erythritol and water content varied. These data are also commensurate in scope with claim 1 since they show compositions having the endpoint values for both erythritol (30 and 60 wt.%) and water (15 and 30 wt.%) as well as comparative compositions having erythritol and water content outside of these ranges.

Provisional Rejection—Obviousness-type Double Patenting

Claims 1-7 were *provisionally* rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over the claims 1-3, 6-8, 10, 13-16, and 19 copending application U.S. 11/512,326. This provisional rejection cannot be sustained because the copending application does not suggest selecting a ratio of components (A) and (B) as defined by Equation (1) as explained above. The copending application has a filing date of 08-30-2006 and the present case was earlier filed on 03-04-2005. Therefore, this provisional rejection should be withdrawn pursuant to MPEP 804(I)(B)(1) upon the identification of allowable subject matter in the present application:

> If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other

grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

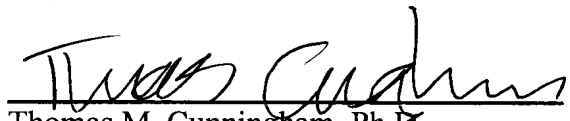
The Applicants submit that the foregoing amendments and remarks address all the remaining rejections and place this application in condition for allowance. Accordingly, this provisional double patenting rejection can no longer be sustained.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Stephen G. Baxter



Thomas M. Cunningham, Ph.D.
Attorney of Record
Reg. No. 45,394

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)